

## § 524.575

(b) *Sponsor*. See No. 063238 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) Cuprimyxin is a broad spectrum antibacterial and antifungal cream for the topical treatment of superficial infections in horses, dogs, and cats caused by bacteria, dermatophytes (*Trichophyton* spp., *Microsporum* spp.) and yeast (*Candida albicans*) affecting skin, hair, and external mucosae.

(2) The cream is applied twice daily to affected areas by rubbing into lesions. Treatment should be continued for a few days after clinical recovery to avoid possible relapses.

(3) After application to cutaneous areas, a change in color from dark green to pink is due to the liberation of free myxin from its copper complex.

(4) If no response is seen within seven days, diagnosis and therapy should be reevaluated. If any adverse local reaction is observed after topical application, discontinue treatment.

(5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 45 FR 56799, Aug. 26, 1980; 66 FR 46706, Sept. 7, 2001]

## § 524.575 Cyclosporine ophthalmic ointment.

(a) *Specifications*. Each gram of ointment contains 2 milligrams of cyclosporine.

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. Apply a 1/4-inch strip of ointment to the affected eye(s) every 12 hours.

(2) *Indications for use*. For management of chronic keratoconjunctivitis sicca (KCS) and chronic superficial keratitis (CSK) in dogs.

(3) *Limitations*. Place ointment directly on cornea or into the conjunctival sac. Safety of use in puppies, pregnant or breeding animals has not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[60 FR 48651, Sept. 20, 1995, as amended at 62 FR 48940, Sept. 18, 1997]

## 21 CFR Ch. I (4–1–05 Edition)

### § 524.590 Diclofenac.

(a) *Specifications*. Each gram of cream contains 10 milligrams diclofenac sodium.

(b) *Sponsor*. See No. 065274 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*. Apply a 5-inch (5") ribbon of cream twice daily over the affected joint for up to 10 days and rub thoroughly into the hair covering the joint until it disappears.

(2) *Indications for use in horses*. For the control of pain and inflammation associated with osteoarthritis in tarsal, carpal, metacarpophalangeal, metatarsophalangeal, and proximal interphalangeal (hock, knee, fetlock and pastern) joints.

(3) *Limitations*. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[69 FR 40767, July 7, 2004]

### § 524.660 Dimethyl sulfoxide ophthalmic and topical dosage forms.

#### § 524.660a Dimethyl sulfoxide solution.

(a) *Specifications*. Dimethyl sulfoxide contains 90 percent of dimethyl sulfoxide and 10 percent of water.

(b) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) It is used or intended for use as a topical application to reduce acute swelling due to trauma:

(i) In horses administered 2 or 3 times daily in an amount not to exceed 100 milliliters per day. Total duration of therapy should not exceed 30 days.

(ii) In dogs administered 3 or 4 times daily in an amount not to exceed 20 milliliters per day. Total duration of therapy should not exceed 14 days.

(2) Not for use in horses and dogs intended for breeding purposes nor in horses slaughtered for food. Other topical medications should only be used when the dimethyl sulfoxide treated area is thoroughly dry. Do not administer by any other route.

(3) For use by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 61 FR 5507, Feb. 13, 1996]